

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No.: 7,052,679)
Inventors: Joshua D. Rabinowitz et al.)
Issue Date: May 30, 2006)
For: DELIVERY OF ANTIPSYCHOTICS)
 THROUGH AN INHALATION)
 ROUTE)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

REQUEST FOR CERTIFICATE OF CORRECTION

Pursuant to 35 U.S.C. § 255 and 37 C.F.R. § 1.323, this is a request for the issuance of a Certificate of Correction in the above-identified patent. Two (2) copies of PTO Form 1050 are appended. The complete Certificate of Correction involves one (1) page.

The mistake identified in the attached Form concerns the systematic (IUPAC) name for the drug loxapine which appears at column 12, lines 3-4 of the patent. The name reads:

2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine.

The name should read:

2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine.

The systematic name for loxapine is well-documented, *e.g.*, in scientifically accepted references such as The Merck Index. *See*, The Merck Index – An Encyclopedia of Chemicals, Drugs and Biologicals, 13th Ed., Maryadele J. O'Neil et al. (Eds.). Merck & Co., Inc. Whitehouse Station, NJ. 2001, p. 1001 (#5609) (attached).

The mistake identified in the attached Form is of a clerical or typographical nature, or of a minor character, and resulted from an error made in good faith by applicants. Therefore, Issuance of a Certificate of Correction correcting this error is requested.

The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to Deposit Account No. 19-5117.

Respectfully submitted,

Date: April 17, 2008

/Katherine Lobel-Rice/
Katherine Lobel-Rice, #58,079
Swanson & Bratschun, L.L.C.
8210 SouthPark Terrace
Littleton, Colorado 80120
Telephone: (303) 268-0066
Facsimile: (303) 268-0065

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 7,052,679 B2

APPLICATION NO.: 10/767,115

ISSUE DATE : May 30, 2006

INVENTOR(S) : Joshua D. Rabinowitz et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, lines 3-4, "2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine" should read
--2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Swanson & Bratschun, LLC
8210 SouthPark Terrace
Littleton, CO 80120

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

THE MERCK INDEX

AN ENCYCLOPEDIA OF
CHEMICALS, DRUGS, AND BIOLOGICALS

THIRTEENTH EDITION

Editorial Staff

Maryadele J. O'Neil, *Senior Editor*

Ann Smith, *Senior Associate Editor*

Patricia E. Heckelman, *Associate Editor*

John R. Obenchain Jr., *Editorial Assistant*

Jo Ann R. Gallipeau, *Technical Assistant*

Mary Ann D'Arecca, *Administrative Associate*

Susan Budavari, *Editor Emeritus*

Published by
Merck Research Laboratories
Division of

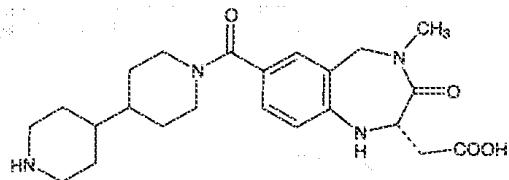
MERCK & CO., INC.

Whitehouse Station, NJ

2001

to Du Pont; D-1). Angiotensin Pharmacol. Exp. Toxicity: A. T. Chiu 2, 1195 (1990); P. C. Wong et al., Symposium 53S (1991). Re. Mcintyre et al., anal effect on men 5, 1582 (2000), 5-6.

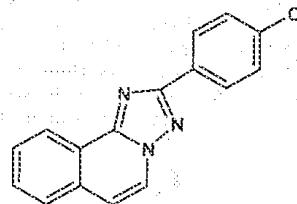
Pont 753; DUP o-Lotan; Oscar ochlorothiazide.



Zwitterionic. $[\alpha]_D = -200.1^\circ$ ($c = 0.5$ in methanol).

THERAP CAT: Antithrombotic.

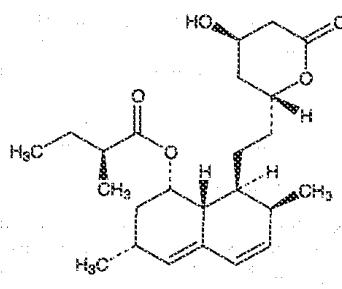
5607. Lotrifén. [66535-86-2] 2-(4-Chlorophenyl)-1,2,4-triazolo[5,1-a]isoquinoline; 2-(*p*-chlorophenyl)-*s*-triazolo[5,1-a]isoquinoline; L-12717; DL-717-FF; Canocenta; Priva-prol. $C_{18}H_{15}ClN_3$; mol wt 279.73. C 68.70%, H 3.60%, Cl 12.67%, N 15.02%. Non-hormonal antifertility agent. Prepn: BE 815498; A. Omodei-Salé et al., US 4075341 (1974, 1978 both to Lepetit). Pharmacokinetics: G. Galliani et al., J. Pharmacobi-Dyn. 5, 55 (1981). Pregnancy-terminating effect in dogs: G. Galliani, A. Omodei-Salé, J. Small Anim. Pract. 23, 295 (1982). Effect on subsequent fertility: G. Galliani et al., IRCS Med. Sci. 12, 433, 435 (1984). Review: A. Assandri et al., Rev. Drug Metab. Drug Interact. 4, 237 (1982).



Crystals mp 238-240°.

THERAP CAT (VET): Abortifacient.

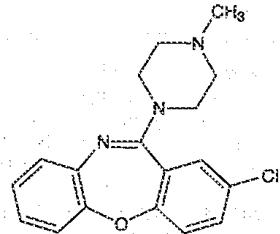
5608. Lovastatin. [75330-75-5] (2S)-2-Methylbutanoic acid (1S,3R,7S,8S,8aR)-1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-[(2R,4R)-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl]ethyl]-1-naphthalenyl ester; (1S,3R,7S,8S,8aR)-1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-[(2R,4R)-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl]ethyl]-1-naphthalenyl (S)-2-methylbutyrate; 1,2,6,7,8,8a-hexahydro- β , δ -dihydroxy-2,6-dimethyl-8-(2-methyl-1-oxobutoxy)-1-naphthaleneheptanoic acid δ -lactone; 2 β ,6 α -dimethyl-8 α -(2-methyl-1-oxobutoxy)mevinic acid lactone; mevinolin; 6 α -methylcompactin; monacolin K; MK-803; Lovalip; Mevacor; Mevinacor; Mevior; Sivior. $C_{24}H_{36}O_5$; mol wt 404.54. C 71.26%, H 8.97%, O 19.77%. Fungal metabolite; potent inhibitor of HMG-CoA reductase, the rate controlling enzyme in cholesterol biosynthesis. Isoin from *Monascus ruber*: A. Endo, J. Antibiot. 32, 852 (1979); from *Aspergillus terreus*: R. L. Monaghan et al., US 4231938 (1980 to Merck & Co.). Structure and biochemical properties: A. W. Alberts et al., Proc. Nat. Acad. Sci. USA 77, 3957 (1980). Total synthesis: M. Hirama, M. Iwashita, Tetrahedron Letters 24, 1811 (1983). Review of syntheses: T. Rosen, C. H. Heathcock, Tetrahedron 42, 4909-4951 (1986). Biosynthesis: M. D. Greenspan, J. B. Yudkovitz, J. Bacteriol. 162, 704 (1985); R. N. Moore et al., J. Am. Chem. Soc. 107, 3694 (1985). HPLC determinants in plasma and bile: R. J. Stubbs et al., J. Chromatog. 383, 438 (1986). Clinical pharmacology: S. M. Grundy, G. L. Vega, J. Lipid Res. 26, 1464 (1985). Clinical comparison with gemfibrozil, q.v.: M. J. Tikkainen et al., Am. J. Cardiol. 62, 35J (1988). Review of clinical experience: J. A. Tobert, Am. J. Cardiol. 62, 28J-34J (1988). Comprehensive description: G. S. Brenner et al., Anal. Profiles Drug Subs. Excip. 21, 277-305 (1992). Prevention of acute coronary events in men and women with average cholesterol levels: J. R. Downs et al., J. Am. Med. Assoc. 279, 1615 (1998).



White crystals, mp (under N_2): 174.5°. $[\alpha]_D^{25} + 323^\circ$ ($c = 0.5$ g in 100 ml acetonitrile). uv max: 231, 238, 247 nm ($A^{\text{1%}} 532, 621, 418$). Solv at room temp (mg/ml): acetone 47, acetonitrile 28, *n*-butanol 7, *i*-butanol 14, chloroform 350, *N,N*-dimethylformamide 90, ethanol 16, methanol 28, *n*-octanol 2, *n*-propanol 11, *i*-propanol 20, water 0.4×10^{-3} . LD₅₀ orally in mice: >1000 mg/kg (Endo).

THERAP CAT: Antihyperlipoproteinemic.

5609. Loxapine. [1977-10-2] 2-Chloro-11-(4-methyl-1-piperazinyl)dibenz[b,f][1,4]oxazepine; oxilapine; CL-62362; S-805; SUM-3170. $C_{18}H_{15}ClN_3O$; mol wt 327.82. C 65.95%, H 5.53%, Cl 10.81%, N 12.82%, O 4.88%. Prepn: NL 64066089 corresp to Schmutz et al., US 3546226 (1964, 1970 both to Wander); *eidem* Helv. Chim. Acta 50, 245 (1967); Coppola, US 3412193 (1968 to Am. Cyanamid). Crystal structure: D. B. Cosulich, F. M. Lovell, Acta Crystallogr. 33B, 1147 (1977). Pharmacology: Schmutz et al., Chim. Ther. 2, 424 (1967); Latimer, J. Pharmacol. Exp. Ther. 166, 151 (1969). Toxicity data: Stille et al., Arzneimittel-Forsch. 15, 841 (1965). Toxicity studies: Mineshita et al., Oyo Yakuri 4, 293 (1970), C.A. 76, 81145v (1972). Review of pharmacology and therapeutic efficacy: R. C. Heel et al., Drugs 15, 198-217 (1978).



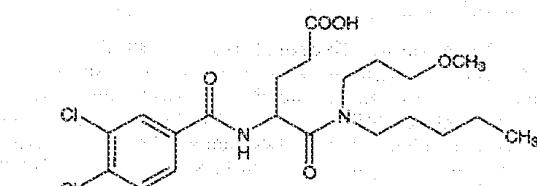
Pale yellowish crystals from petr ether, mp 109-110°. LD₅₀ orally in mice: 65 mg/kg (Stille).

Hydrochloride. Loxitane C. $C_{18}H_{15}ClN_3O \cdot HCl$; mol wt 364.28.

Succinate. [27833-64-3] CL-71563; Loxapac; Loxitane. $C_{18}H_{18}ClN_3O \cdot C_4H_6O_4$; mol wt 445.90.

THERAP CAT: Anxiolytic.

5610. Loxiglumide. [107097-80-3] 4-[(3,4-Dichlorobenzoyl)amino]-5-[(3-methoxypropyl)pentylamino]-5-oxopentanoic acid; (\pm)-4-(3,4-dichlorobenzamido)-*N*-(3-methoxypropyl)-*N*-pentylglutamic acid; CR-1505. $C_{21}H_{26}Cl_2N_2O_5$; mol wt 461.39. C 54.67%, H 6.55%, Cl 15.37%, N 6.07%, O 17.34%. Cholecystokinin A (CCK-A) antagonist. Prepn: F. Makovec et al., WO 87 03869; *eidem*, US 4769389 (1987, 1988 both to Rotta). Pharmacology and receptor binding: I. Setnikar et al., Arzneimittel-Forsch. 37, 703 (1987). Pharmacokinetics:



UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 7,052,679 B2

APPLICATION NO.: 10/767,115

ISSUE DATE : May 30, 2006

INVENTOR(S) : Joshua D. Rabinowitz et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, lines 3-4, "2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine" should read
--2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Swanson & Bratschun, LLC
8210 SouthPark Terrace
Littleton, CO 80120

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.